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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/075,918	02/13/2002	Nicole Chantel Barvian	A0000426-01-CFP	9234

28880 7590 10/22/2003

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ANN ARBOR, MI 48105

EXAMINER
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OH, TAYLOR V

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 10/22/2003

6

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/075,918

Applicant(s)

BARVIAN ET AL.

Examiner

Taylor Victor Oh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,5,7 and 10-17 is/are rejected.
- 7) ☐ Claim(s) 3,4,6,8 and 9 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2&3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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The Status of Claims:

Claims 1-17 are pending.

Claims 1-2, 5, 7, and 10-17 have been rejected.

Claims 3-4, 6, and 8 and 9 have been objected.

Election/Restrictions

Applicant's election with traverse of Group II (claims 1- 17) in Paper No. 5 is acknowledged. In response to applicants' request, Group I and Group II are specified in details in the followings.

In Group II , Claims 1-17 are related to the side chain groups of isophthalic acid derivatives consisted of different kinds of heterocycles; for examples, Claims 1-3, 5, and 6 have described that the definition of  $R^4$  and  $R^5$  independently is only  $(CH_2)_n$  heteroaryl or  $R^4$  and  $R^5$  when taken together with nitrogen to which they are attached complete a 3- to 8-membered ring, optionally containing a heteroatom selected from O, S, NH, and optionally substituted or unsubstituted in the presence of all the other limitations as before; Claim 4 has described the definition of each  $R^4$  and  $R^5$  independently is only  $(CH_2)_n$  heteroaryl or  $R^4$  and  $R^5$  when taken together with nitrogen to which they are attached complete a 3- to 8-membered ring, optionally containing a

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heteroatom selected from O, S, NH, and optionally substituted or unsubstituted;

furthermore, each of  $R^1$  and  $R^2$  and  $R^3$  independently is only  $NR^4 R^5$  in which each of  $R^4$  and  $R^5$  has been defined in the above.

Lastly, Claim 7 contains the only compounds containing heterocyclic groups, such as benzothiadiazol, pyridin, benzodioxol, and furan.

In Group I, Claims 1-17 are related to the side chain groups of isophthalic acid derivatives consisted of different kinds of non-heterocyclic groups; for an example, claims 1-7 are related to all the limitations regarding the defined  $R^1$ ,  $R^2$ ,  $R^3$ , and  $R^4$  with an exception of what has been defined for Group II.

Claims 1-17 (Group I) are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected groups I, there being no allowable generic or linking claim.

#### DETAILED ACTION

1. Claims 1-17 (Group II) are under consideration in this Office Action.

Priority

2. None.

Drawings

3. None.

Claim Objections

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Claims 3-4, 6 are objected to because of the following informalities: they contain some of the Group I limitations which have been withdrawn from further consideration. Appropriate correction is required.

### Claim Rejections - 35 USC § 112

Claims 11 and 12 are rejected under 35 U.S.C. 112, first paragraph. Claims 11 and 12 are a method claim for treating a disease and a cancer. The term "a disease" includes any cancer. The specification falls short because data essential for treating cancers is not described in the specification. In the absence of specific malignant tumors or otherwise, data showing inhibition of the multiplication of cancer cells, such a broad assertion is not believable in view of the contemporary knowledge of the art. 34 USPQ 2d, 1436 (Fed Cir. 1995). See also, MPEP 2107.01, 2107.02, 2107.03, 2164.01©, 2164.04, 2164.07.

Moreover, the claim sets forth the treatment of cancer generally. However, there are more than 3000 cancers. Applicants have not identified a specific compound capable of treating "cancers" broadly. Thus, the existence of such a "silver bullet" is contrary to our present understanding in oncology. Even the most broadly effective anti-tumor agents are only effective against a small fraction of the vast number of different cancers known. This is true in part because cancers arise from a wide variety of sources, such as viruses (e.g. EBV, HHV-8, and HTLV-1), exposure to chemicals such as tobacco tars, genetic disorders, ionizing radiation, and a wide variety of failures

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of the body's cell growth regulatory mechanisms. Different types of cancers affect different organs and have different methods of growth and harm to the body, and different vulnerabilities. Thus, it is beyond the skill of oncologists today to get an agent to be effective against cancers generally, evidence that the level of skill in this art is low relative to the difficulty of such a task. See also, *In re Joller*, 206 USPQ 885(CCPA 1980).

Claims 10-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "a compound of Formula I" has not been defined in the claims and is outside the scope of the compounds of Formula I.

The compound of Formula I has many substituents, such as  $R^4$  and  $R^5$  independently is only  $(CH_2)_n$  heteroaryl or  $R^4$  and  $R^5$  when taken together with nitrogen to which they are attached complete a 3- to 8-membered ring, optionally containing a heteroatom selected from O, S, NH, and optionally substituted or unsubstituted in the presence of all the other limitations including each of  $R^1$  and  $R^2$  and  $R^3$  independently which is only  $NR^4 R^5$ . These and other limitations of the compound of Formula I have been missed out and Claim 1 has described a full description of the compound of Formula I.

Therefore, an appropriate correction is required.

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### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 5 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated clearly by (JP-405193260).

Japanese patent (405193260) discloses an isophthalic acid bis-(1,3-benzodioxo-5-ylmethyl) ester compound (see page 531, compound # 0013).

This is identical with the claims.

Claims 8 and 9 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 703-305-0809. The examiner can normally be reached on 8:30-5:00.

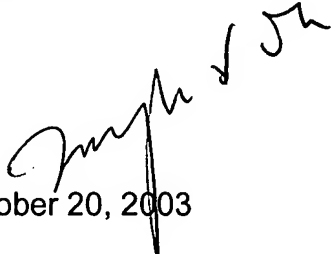
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on 703-308-4698. The fax phone numbers

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for the organization where this application or proceeding is assigned are 703-308-2742

for regular communications and 703-305-7401 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

  
October 20, 2003